

K830834 NEGATIVE URINE CONTROLApr 12, 1983
27 days to decisionK830834 · Product code: **JJW** · Chemistry
Source: <https://www.510kdatabase.net/k830834/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinalysis Controls (assayed And Unassayed) (JJW)
Date received	Mar 16, 1983
Decision date	Apr 12, 1983
Days to decision	27 days
Third-party review	No

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
510(k) history	280 submissions · 280 cleared · 1978-2013

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Device record: <https://www.510kdatabase.net/k830834/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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